Consumers
Health Forum
of Australia

13 June 2013

Management and Co-ordination Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Feasibility of a new-to-market risk communication scheme for therapeutic goods

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission into the Therapeutic Goods Administration (TGA)'s consultation on the *Feasibility of a new-to-market risk communication scheme for therapeutic goods Workshop Briefing Paper* (the Paper).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Australian health consumers have a strong interest in the regulation of medicines and medical devices in Australia. Pharmacovigilance and post-market monitoring of medical devices are critical mechanisms that can greatly contribute to consumer safety. As the ultimate end users, consumers must have confidence that the regulatory oversight processes for therapeutic products is robust and vigilant.

CHF accepts that the purpose of the Paper is to consult on the feasibility of a new-to-market risk communication scheme for therapeutic goods. However, the feasibility and effectiveness of such a framework cannot be understood in isolation from the prevailing issues associated with the regulatory framework that underpins it.

While CHF welcomes a new-to-market risk communication scheme as proposed, CHF's comments highlight our concerns about the current pharmacovigilance process, the post-market monitoring of medical devices, and adverse event reporting.

Feasibility of a new to market risk communication scheme

CHF provides in-principle support for the introduction of a new-to-market risk communication scheme for therapeutic goods, based on the Black Triangle scheme that operates in the United Kingdom. However, CHF would need to see further detail about how the scheme might operate in Australia, particularly how consumers would be made aware of the existence of such a scheme and how evaluation of the scheme would be conducted, before fully supporting its establishment.

PO Box 3099, Manuka ACT 2603 ▪ Unit 9, 11 National Circuit, Barton ACT 2600
Tel: (02) 6273 5444 Fax: (02) 6273 5888 Email: info@chf.org.au Web: www.chf.org.au
ABN 82 146 988 927

CHF appreciates the significant reform agenda currently being carried out by the TGA; however, to date, consumers have not been well-informed of the TGA's activities in regulating therapeutic goods in Australia. With this in mind, ***CHF recommends that the TGA conduct an extensive consumer awareness campaign on the implications and requirements associated with using or prescribing a product that is on the new-to-market risk communication scheme.***

CHF accepts that certain products may have a higher risk profile than others and as a result should be monitored more closely. However, CHF is concerned that the development of a symbol to indicate that a product is to be monitored more closely might give consumers the impression that products without the symbol carry less risk. The Paper notes that limited information is known about a therapeutic product early in its lifecycle. It will be important to convey this fact to consumers to ensure that they are aware of the nature of *all* new products entering the market, and not just products included on the scheme. ***CHF recommends that a consumer awareness campaign to promote a new-to-market risk communication scheme include information about the risks associated with all products entering the market.***

Pharmacovigilance

A new-to-market risk communication scheme needs to be underpinned by increased regulatory powers for the TGA to conduct spot audits on pharmaceutical companies' compliance with pharmacovigilance requirements.

In a letter to the Hon Catherine King MP, former Parliamentary Secretary for Health and Ageing, dated 16 October 2012, CHF outlined its concern about the limited powers the TGA has to conduct spot audits. If the TGA has no power to monitor whether companies are complying with requirements to report serious or unusual adverse events, maintain records of all adverse event reports received and inform the TGA if any patterns emerge, consumers can have little confidence that companies are actually complying with these requirements.

Given that a significant percentage of adverse events are reported by and through pharmaceutical companies, a new-to-market risk communication scheme depends greatly on how well pharmaceutical companies adhere to their pharmacovigilance requirements, legislated or otherwise. ***CHF recommends greater regulatory power for the TGA to conduct spot audits on pharmaceutical companies' compliance with pharmacovigilance requirements.***

Post-market monitoring of Medical Devices

Consumers are particularly concerned with processes for managing adverse events and failures, and the poor post-market monitoring of medical devices. Unlike medicine, which a consumer may simply stop taking, issues relating to faulty medical devices that are implanted into the body are much more difficult to remedy. This is why monitoring consumer experience with medical devices and establishing trends that may have adverse safety implications as early as possible is important. In instances where a faulty device is implanted, it is not a straightforward matter to remove the device if something goes wrong. It requires traumatic, invasive revision surgery that puts the consumer's health, and sometimes their life, at risk.

The TGA's approach to risk minimisation means that post-market surveillance is critical to ensuring the safety of medical devices, as in many cases it is not until devices are on the market that failures become apparent. Contemporary examples of the failure of the therapeutic goods regulation system are evident in the case of Poly Implant Prostheses and ASR hip implants.

PO Box 3099, Manuka ACT 2603 ■ Unit 9, 11 National Circuit, Barton ACT 2600
Tel: (02) 6273 5444 Fax: (02) 6273 5888 Email: info@chf.org.au Web: www.chf.org.au
ABN 82 146 988 927

Consumers want to know that when a device is failing at unacceptable levels, action will be taken promptly to contact and assist those who are already using the device and to prevent the use of the device in any further procedures. A robust new-to-market risk communication scheme, so long as consumers understand its purpose, will contribute to enhanced monitoring of medical devices. Further, medical devices on such a scheme would need to operate differently from pharmaceuticals, given that medical device faults may only arise years after they are implanted. ***CHF recommends that medical devices remain on the scheme for a significantly longer time than medicines.***

Adverse event reporting

Adverse event monitoring and reporting plays an essential role in the safe and effective use of medicines. In 2011, CHF consulted consumers on the topic of adverse events in the community.[1] Consumers who participated were generally not aware of these mechanisms for reporting adverse events. The situation will not change until consumers are encouraged and informed to report directly to the TGA, rather than through a health professional as is currently the case.

Participants felt that current adverse event reporting mechanisms do not adequately capture consumers' experiences of medicine use and that there is little scope within these mechanisms for reporting the qualitative experiences of consumers with medicines, such as the overall impact of medicines and medical devices on quality of life. The current reporting system was seen as being dominated by clinicians, prescribers and industry, who often interpreted and filtered the information provided by consumers in a way which did not accurately reflect consumer experience. ***CHF recommends that a new-to-market risk communication scheme be supported by mechanisms to encourage consumers to report directly to the TGA.***

CHF appreciates the opportunity to provide a submission to the paper. Please contact CHF Project and Communications Officer, Mr Carlo Malaca, if you would like to discuss this submission in more detail.

Yours sincerely,

[redacted]

Carol Bennett
CHIEF EXECUTIVE OFFICER

[1] Consumers Health Forum of Australia's Community and Quality Use of Medicines Project in 2011.

PO Box 3099, Manuka ACT 2603 ■ Unit 9, 11 National Circuit, Barton ACT 2600
Tel: (02) 6273 5444 Fax: (02) 6273 5888 Email: info@chf.org.au Web: www.chf.org.au
ABN 82 146 988 927